Non-interventional, post-authorization safety study (PASS) of patients treated with commercially available liso-cel (lisocabtagene maraleucel) for large B-cell lymphomas (JCAR017-BCM-005)

First published: 20/03/2023

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/103856

EU PAS number

EUPAS103855

Study ID

103856

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Croatia
- [ ] Czechia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

The purpose of this PASS is to further characterize the safety profile of liso-cel in the postmarketing setting. This study will include patients from existing independent registries, such as, but not limited to, the European Society for Blood and Marrow Transplantation (EBMT) and the Center for International Blood and Marrow Transplant Research (CIBMTR). The JCAR017-BCM-005 study will be part of the overall liso-cel Risk Management Plan (RMP) including any required regional Pharmacovigilance Plan (PVP) outside the European Union (EU).

Study status

Ongoing

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Center for International Blood and Marrow Transplant Research (CIBMTR)

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Last updated: 01/02/2024

Institution

CIBMTR United States

Networks

EBMT

Contact details

Study institution contact

Transparency and Disclosure Lead

Study contact

ctt.group@bms.com

Primary lead investigator

Montserrat Miret

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/08/2022

Actual: 18/08/2022

Study start date

Planned: 18/03/2023

Actual: 17/03/2023

Data analysis start date

Planned: 18/03/2023

Actual: 17/03/2023

Date of interim report, if expected

Planned: 04/02/2028

Date of final study report

Planned: 31/12/2043

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

Study protocol

jcar017-bcm-005-pass-prot 30-aug-2022-redacted-v2.pdf(736.05 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/C/PSP/S/0098.1

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The main objective is to the incidence and severity of selected adverse drug reactions (ADRs), as outlined in the Summary of Product Characteristics (SmPC), in patients treated with liso-cel in the postmarketing setting and to monitor for potential clinically important adverse events (AEs) that have not yet been identified as part of the liso-cel safety profile.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BREYANZI

Medical condition to be studied

Follicular lymphoma

Additional medical condition(s)

relapsed/refractory diffuse large B-cell lymphoma,primary mediastinal B-cell lymphoma

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

750

Study design details

Outcomes

Secondary malignancies Cytokine release syndrome (CRS) all grades Neurotoxicities all grades Prolonged cytopenias Pregnancy outcome Other AEs considered related to liso-cel treatment (Grade ≥ 3, where applicable), Overall response rate (ORR) Complete response rate (CRR) Duration of response (DoR) Progression-free survival (PFS) Overall survival (OS) Time to next treatment (TTNT)

Data analysis plan

Results will be analyzed and reported descriptively and no formal hypothesis testing is intended. Summary statistics will consist of the number and percentage of patients in each category for discrete variables, whereas for

continuous variables the sample size, mean, median, standard deviation, minimum, and maximum will be given. For the primary safety endpoints, incidence proportions and incidence rates will be calculated with the appropriate time periods and methods, analyses will be carried out both with and without accounting for competing risks. For the secondary effectiveness endpoints, Kaplan-Meier estimates and curves will be generated.

Data management

Data sources

Data source(s), other

CIBMTR United States, EBMT

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No